



HCCA New York Regional Conference

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Identifying and Managing Compliance Risk

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- Lynn Stansel – VP & Counsel – Montefiore Medicine Academic Health System
- Joel Dziengielewski – Director - Navigant



1



Introductions

Your Speakers Today:

- Margaret J. Davino, Esq. – Partner – Fox Rothschild
- Lynn Stansel – VP & Counsel – Montefiore Medicine Academic Health System
- Joel Dziengielewski – Director - Navigant



2

Session Topics and Objectives

The Risk Assessment Process

- Drivers of the risk assessment process
- Provide you with an overview of the risk assessment process
- Provide you with a methodology for conducting a risk assessment
- Understanding appropriate laws and regulations

Planning for the Risk Assessment

- Determining the scope of the risk assessment
- Help you get buy in from the C-Suite
- Determining the list of participants

Conducting the Risk Assessment

- Determining relevant sources for the risk assessment
- Determining the list of participants
- Getting meaningful and comprehensive participation
- Compiling the results
- When the risk assessment uncovers legal concerns

Reporting the Results

- Reporting to participants, the C-Suite and the Board of Directors
- Appropriate documentation

Taking Action as to the Results

- Determining and Implementing Next Steps
- Correcting issues / Reporting obligations ?

3

3

The Risk Assessment Process

Drivers of the risk assessment process

- OIG Work Plan
- Federal Sentencing Guidelines
- Compliance Program Guidance Documents
- Current industry (sector) risk topics
- Internal issues

4

4

The Risk Assessment Process

An overview of the risk assessment process

- Considering appropriate laws
 - Anti-kickback statute
 - Stark law
 - Civil monetary penalties
- Planning & communicating
- Under privilege or not under privilege and Kovel letter
- When in-house attorney work product may be protected
- In-house or utilizing an outside entity
- Identification of risks
- Categorizing Risks – High / Medium / Low

Determining the best methodology for conducting your risk assessment

5

5

Planning for the Risk Assessment

Planning for the Risk Assessment

- Determining the scope of the risk assessment
 - Enterprise wide or limited to compliance
 - Targeted risk assessment
- Help you get buy in from the C-Suite
 - Tone at the top and associated messaging
- Determining the list of participants
 - High level
 - Mid level
 - Other
 - Targeted participants
- Timing and time frame
 - When and how long ?
 - Statute of limitations
- Internal Complaints (whistleblowers?)
- External Complaints
- Regulatory involvement

6

6

Conducting the Risk Assessment

Conducting the Risk Assessment

- Determining relevant sources for the risk assessment
 - OIG Work Plan
 - Past audit results
 - Current industry hot topics
 - Laws and regulations
- How to conduct interviews
 - One on one vs Group or joint
 - Surveys
 - Anonymous Voting Technology
- Getting meaningful and comprehensive participation
 - Assuring anonymity
 - Open ended questions

7

7

Conducting the Risk Assessment

- What if a legal issue is identified?
 - Facts versus conclusions
 - Documentation
- Compiling the results
 - Validating information once compiled
 - Ensuring accurate reporting of information gathered
 - Utilizing a methodology to determine prioritizations
 - Determining the best format for communicating
 - Extent of documentation
 - Attorney-client privilege

8

8

Reporting the Results

Reporting the Results

- Reporting to participants
- The Management level Compliance Committee
- The C-Suite
- The Board of Directors level Compliance Committee

- What to report to each group
- Documentation
- Sharing of information/documentation

9

9

Taking Action as to the Results

Determine action necessary

- Considerations with legal issues, e.g., unsigned contracts, above fair market value arrangements, etc.
- Reporting issues
 - Stark disclosures
 - Anti-kickback disclosures
 - HIPAA disclosures
 - Reporting personnel to OPMC/OPD

Following up on the Results

- Determining and Implementing Next Steps
 - Accountable individuals
 - Developing Corrective Action Plans
 - Monitoring Corrective Action Plans
 - Reporting out on Corrective Action Plans

10

10

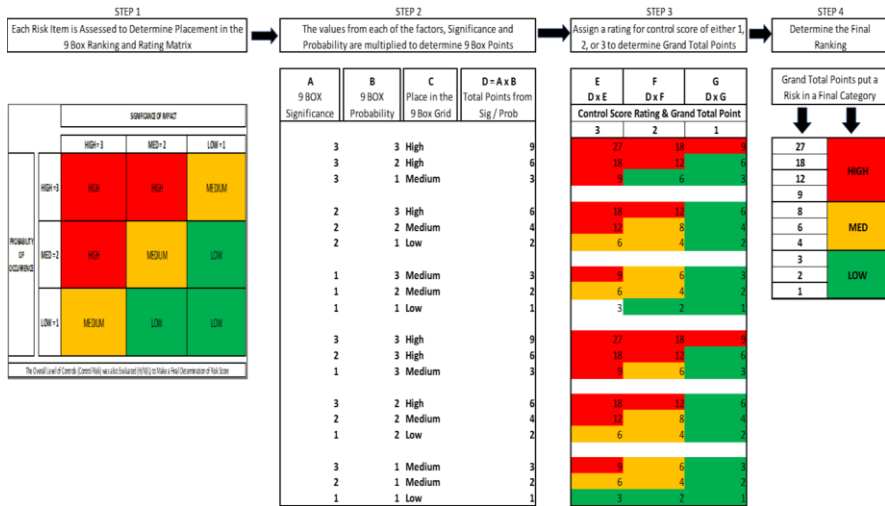
Tools for your Consideration and Use

1. Multi-Box Scoring Methodology - Likelihood / Impact / Controls Assessment
2. Corporate Compliance / HIPAA Likelihood Calculator
3. Risk Assessment – Sample Likelihood / Severity Factors
4. Drug Waste of Single-Use Vial Drugs

11

11

Multi-Box Scoring Methodology Likelihood / Impact / Controls Assessment



12

12

Corporate Compliance / HIPAA Likelihood Calculator

Corporate Compliance / HIPAA Likelihood Calculator

	Criteria	Point Value	Points
L I K E L Y H O O D	On OIG Work Plan	10	0
	ON OIG Work Plan	10	0
	External Audit w / Negative Finding	5-20	0
	1 External Audit w / Negative Finding	5	0
	2+ Internal Audits w / Negative Findings	5	0
	High Volume (Hotline Cases, HIPAA Incidents, etc)		
	Reputational Risk	10	0
	Legal / Regulatory Risk	10	0
	Financial Risk	10	0
	Other Factors - Compliance Program Guidance / OCR, Qui Tam, etc.	10	0
	Max Points	100	0

LIKELIHOOD LEGEND
Highly Unlikely = 5
Unlikely = 10-15
Moderate = 20-45
Likely = 50-90
Almost Certain = 90+

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13

Risk Assessment Sample Likelihood / Severity Factors

		Compliance Risk Assessment				
		Minor (Some disruption possible / or liabilities up to \$500K)	Moderate (Significant time / resources required and/or liabilities between \$500K - \$9.9M)	Major (Operations severely impacted, and /or liabilities between \$10M - \$24.9M)	Severe (Operations severely impacted, and /or liabilities between \$25M - \$50M)	Critical (Business survival at risk, liabilities greater than \$50M)
		Consequences				
L I K E L Y H O O D	Almost Certain (e.g. >90%)	High	High	Extreme	Extreme	Extreme
	Likely (e.g. between 50 & 90%)	Moderate	High	High	Extreme	Extreme
	Moderate (e.g. between 10 & 50%)	Low	Moderate	High	Extreme	Extreme
	Unlikely (e.g. between 3 & 10%)	Low	Low	Moderate	High	Extreme
	Highly Unlikely (e.g. < 3% chance)	Low	Low	Moderate	High	Extreme

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14

Drug Waste of Single-Use Vial Drugs

Description: Effective January 1, 2017, claims for discarded drugs or biologicals amount not administered to any patient shall be submitted using the JW modifier. Also, effective January 1, 2017, providers must document the discarded drugs and biologicals in the patient's medical record. This review will focus on whether the documentation in the medical record supports the use of the JW modifier. We will also determine the amount of waste for the 20 single-use vial drugs with the highest amount paid for waste as identified by the JW modifier and evaluate whether a different size vial could have been used instead.

Scope: Review a sample of 100 billed claims with the JW modifier attached

Quarter: 2

Responsible Person(s):

Risk Rating: Moderate

Benefiting Department:

Effectiveness Measure: Improved documentation of waste, improved accuracy of vial size, improved accuracy rate percentage

Additional Comment:

Supporting Documentation:

Attachment 1 – Compliance Risk Assessment – Drug Waste

Attachment 2 - Medicare Program JW Modifier: Drug/Biological Amount Discarded/Not

Administered To Any Patient Frequently Asked Questions

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>

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15